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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,503	02/08/2006	Stephen McMahon	HMP01 004	6554

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EXAMINER	
HOLCOMB, MARK	

ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,503	MCMAHON ET AL.	
	Examiner	Art Unit	
	MARK HOLCOMB	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10 January 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 25 May 2005, which claims priority to a PCT filing date of 27 November 2003, and a foreign application priority date of 27 November 2002.

2. Claims 1-31 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statement(s) (IDS) submitted on 10 January 2006 has been considered by the Examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 7 and 16** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation *wherein the recorded particulars of the selected participants in the ordered registration information are restricted to predetermined trial administrators and auditors*. It is unclear what the Applicant is attempting to claim with this limitation. For purposes of examination, the Examiner interprets this limitation to read *wherein electronic access to the recorded particulars of the selected participants in the ordered registration information are restricted to predetermined trial administrators and auditors*.

Claim 16 recites the limitation *being configured to accepted on predetermined data.* It is unclear what the Applicant is attempting to claim with this limitation. For purposes of examination, the Examiner interprets this limitation to read *being configured to allow access based ~~accepted~~ on predetermined data.*

Appropriate clarification is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

9. **Claims 1-10 and 15-28** are rejected as being unpatentable over McAlindon et al. (U.S. Patent Number 7,251,609 B1), hereinafter McAlindon, in view of Manning et al. (U.S. Pre-Grant Publication Number 2003/0220849 A1), hereinafter Manning.

As per **claims 1 and 21**, McAlindon discloses a *method of conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the method including the steps of:*

- *establishing an electronic database in communication with one or more remote computers* (see at least McAlindon, Fig. 3 and corresponding text)*;*
- *entering predetermined trial parameters of the conduct of the clinical trial into the database* (see at least McAlindon, Fig. 6 and corresponding text)*;*
- *programming the database and remote computers to provide a predetermined interface for accepting predetermined information relating to the trial being entered by trial participants, administrators and/or auditors* (see at least McAlindon, Fig. 8A and corresponding text)*;*
- *recording particulars of the trial participants and forming ordered registration information on the database* (see at least McAlindon, Fig. 2 and corresponding text)*;*

- *forming randomised particulars of the trial participants in the database from the ordered registration information, the randomised particulars including the allocation of an identifier label* (see at least McAlindon, Col. 23, line 58 to Col. 24 line 13; Examiner notes that Merriam Webster's Online Dictionary defines "label" as "a descriptive or identifying word or phrase." The noted reference is labeling participants as "active test substance" or "placebo".)*;*
- *assigning the device or method or substance of treatment to the randomised particulars of each trial participant* (see at least McAlindon, Col. 23, line 58 to Col. 24 line 27)*;*
- *entering trial data via the predetermined interface into the database by an authorized trial participant* (see at least McAlindon, Fig. 8A and corresponding text)*;*
- *producing a report of data entered onto the database in response to predetermined reporting conditions* (see at least McAlindon, Fig. 6, #162 and corresponding text)*;*
- *and terminating the clinical trial in response to predetermined termination conditions* (see at least McAlindon, Col. 24, lines 15-16).

McAlindon fails to disclose, but Manning succeeds in disclosing *controlling and tracking the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a method or substance inventory record on the database* (see

at least Manning, Fig. 4A to 4G and corresponding text). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of McAlindon with the system for projecting and tracking supplies in clinical trials of Manning because to do so would result in a method for conducting clinical trials over the internet in which it is possible "to plan, project, and allocate the precise quantities of drug substance, drug product, and clinical supply packages for each clinical trial" (Manning, paragraph 50).

As per **claims 2 and 22**, McAlindon/Manning disclose the method and system of claims 1 and 21, respectively, as detailed above. McAlindon also discloses a method and system *for conducting a clinical trial of a pharmaceutical substance* (see at least McAlindon, Col. 12, lines 44-67).

As per **claim 3**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the database and remote computers communicate via internet communications* (see at least McAlindon, Col. 2, lines 44-67).

As per **claim 3**, McAlindon/Manning disclose the method of claim 2, detailed above. McAlindon also discloses a method *wherein the predetermined trial parameters include the dosage rates of the pharmaceutical substance to be given to the selected trial participants* (see at least McAlindon, Col. 23, lines 59-67).

As per **claim 5**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the trial data is entered onto the remote computer or the database and wherein only specific volumes and forms of the data are acceptable by the remote computer or central database* (see at least McAlindon, Fig. 9 and corresponding text).

As per **claim 6**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the trial administrators have access to view any entered data or add any predetermined data to the information in the database, and the trial auditors have access to view any entered information in the database* (see at least McAlindon, Fig. 6 and corresponding text, and Col. 25).

As per **claim 7**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the recorded particulars of the selected participants in the ordered registration information are restricted to predetermined trial administrators and auditors* (see at least McAlindon, Col. 15, line 47 to Col. 16 line 14).

As per **claim 8**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the randomised particulars of the selected*

trial participants and trial information relating to those participants are available to all trial participants (see at least McAlindon, Col. 7, lines 24-37).

As per **claim 9**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *including the step of generating reminders from the database at predetermined times after trial data is entered, the reminders being displayed to predetermined trial participants upon access to the remote computers or the database* (see at least McAlindon, Fig. 4 and corresponding text, and Col. 6, lines 16-40, and Col. 24, lines 15-49).

As per **claim 10**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *wherein the trial report of entered data reports on all data entered into the database at a predetermined time or in response to the entry of specific data types or quantities* (see at least McAlindon, Fig. 6, #162 and corresponding text).

As per **claim 15**, McAlindon/Manning disclose the method of claim 2, detailed above. McAlindon also discloses a method *wherein the trial termination conditions include a lapsing of a predetermined time, consumption of a predetermined amount of pharmaceutical substance by one or more trial participants, or the occurrence of an adverse event of a trial participant* (see at least McAlindon, Col. 24 lines 15-16).

As per **claim 16**, McAlindon/Manning disclose the method of claim 1, detailed above. McAlindon also discloses a method *including a plurality of remote computers each being disposed at individual sites remote from the database and being configured to accepted on predetermined data* (see at least McAlindon, Col. 25, lines 1-49).

As per **claim 17**, McAlindon/Manning disclose the method of claim 2, detailed above. McAlindon also discloses a method *wherein a plurality of pharmaceutical substances are simultaneously trialed and controlled by the database* (see at least McAlindon, McAlindon, Col. 12, lines 44-67, and Fig. 7 and corresponding text).

As per **claims 18 and 26**, McAlindon/Manning disclose the method and system of claims 1 and 21, respectively, as detailed above. McAlindon also discloses a method and system *wherein the remote computers are selected from the group consisting of: personal digital assistants, laptop computers, desktop computers, tablet personal computers, mobile telephones, pagers and dedicated computing devices* (see at least McAlindon, Col. 6, line 52).

As per **claims 19 and 27**, McAlindon/Manning disclose the method and system of claims 1 and 21, respectively, as detailed above. McAlindon also discloses a method and system *wherein the remote computers and electronic database communicate by*

wireless, electrical cable and/or optical fibre networks (see at least McAlindon, Col. 12, lines 44-67).

As per **claims 20 and 28**, McAlindon/Manning disclose the method and system of claims 1 and 21, respectively, as detailed above. McAlindon also discloses a method and system *wherein the electronic database includes a computer server in combination with a data storage device* (see at least McAlindon, Fig. 3 and corresponding text).

As per **claim 23**, McAlindon/Manning disclose the system of claim 22, detailed above. McAlindon also discloses a system *wherein the database is configured to receive and record information relating to the trial participants and also to form randomised particulars of the trial participants in the database including the determination of which trial participants receive the pharmaceutical substance and which receive a placebo* (see at least McAlindon, Fig. 2 and corresponding text, and Col. 23, line 58 to Col. 24 line 13).

As per **claim 24**, McAlindon/Manning disclose the system of claim 21, detailed above. McAlindon also discloses a system *wherein the database is configured to produce a report of data entered into the database relating to the trial* (see at least McAlindon, Fig. 6, #162 and corresponding text).

As per **claim 25**, McAlindon/Manning disclose the system of claim 25, detailed above. McAlindon also discloses a system *wherein the database is configured to generate reminders to the trial administrators at a predetermined time after trial data is entered or the trial commenced, the reminders being displayed upon the trial administrators accessing a remote computer* (see at least McAlindon, Fig. 2, #68 and corresponding text).

10. **Claim 11** is rejected as being unpatentable over McAlindon in view of Manning, further in view of Manning.

As per **claim 11**, McAlindon/Manning disclose the method of claim 2, detailed above. McAlindon fails to disclose, but Manning succeeds in disclosing a method *wherein the step of controlling and tracking the movement of the pharmaceutical substances and recording the pharmaceutical substance inventory record on the database further includes the step of selectively establishing communication with the pharmaceutical substance supplier and placing an electronic order* (see at least Manning, Fig. 4E and corresponding text). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of McAlindon/Manning with the system for projecting and tracking supplies in clinical trials of Manning because to do so would result in a method for conducting clinical trials over the internet in which it is possible "to

plan, project, and allocate the precise quantities of drug substance, drug product, and clinical supply packages for each clinical trial" (Manning, paragraph 50).

11. **Claims 12 and 29** are rejected as being unpatentable over McAlindon in view of Manning, further in view of Thangaraj et al. (U.S. Pre-Grant Publication Number 2003/0208378 A1), hereinafter Thangaraj.

As per **claims 12 and 29**, McAlindon/Manning disclose the method and system of claims 1 and 21, respectively, as detailed above. McAlindon fails to disclose, but Thangaraj succeeds in disclosing a method and system *including the steps of:*

- *providing one or more local trial administration centres for conducting the clinical trial* (see at least Thangaraj, paragraph 75)*;*
- *assigning one or more trial participants to each local trial administration centre* (see at least Thangaraj, paragraph 75)*;*
- *determining a payment to each local trial administration centre for conducting the clinical trial* (see at least Thangaraj, paragraphs 105-120)*;*
- *and effecting the determined payment to each local trial administration centre at predetermined times from the commencement of the clinical trial* (see at least Thangaraj, paragraphs 105-120)*.*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of McAlindon/Manning with the clinical trial management system of Thangaraj because to do so would result in a method for conducting clinical trials over the internet that would "maximize the upfront investment dollar, permitting the support of a greater number of drug candidates, and … greatly increase the return on that investment on the back end through increased sales" (Thangaraj, paragraph 3).

12. **Claims 13, 14, 30 and 31** are rejected as being unpatentable over McAlindon in view of Manning in view of Thangaraj, further in view of Thangaraj.

As per **claims 13 and 30**, McAlindon/Manning/Thangaraj disclose the method and system of claims 12 and 29, respectively, as detailed above. McAlindon fails to disclose, but Thangaraj succeeds in disclosing a method and system *wherein the determined payments are determined in response to types of treatment delivered to trial participants and a standard amount per patient per clinical trial visit* (see at least Thangaraj, paragraphs 105-120). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of McAlindon/Manning/Thangaraj with the clinical trial management system of Thangaraj because to do so would result in a method for conducting clinical trials over the internet that would "maximize the upfront investment dollar, permitting the support of a greater

number of drug candidates, and … greatly increase the return on that investment on the back end through increased sales" (Thangaraj, paragraph 3).

As per **claims 14 and 31**, McAlindon/Manning/Thangaraj disclose the method and system of claims 12 and 29, respectively, as detailed above. McAlindon fails to disclose, but Thangaraj succeeds in disclosing a method and system *including the step of providing financial reports relating to the determined payments including payments earned by the local trial administration centres, payments made thereto, payments outstanding to each local trial administration centre, and over-payments previously made to any local trial administration centre* (see at least Thangaraj, paragraphs 105-120). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of McAlindon/Manning/Thangaraj with the clinical trial management system of Thangaraj because to do so would result in a method for conducting clinical trials over the internet that would "maximize the upfront investment dollar, permitting the support of a greater number of drug candidates, and … greatly increase the return on that investment on the back end through increased sales" (Thangaraj, paragraph 3).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Mark Holcomb,** whose telephone number is **571.270.1382.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor,** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

/M. H./
Examiner
28 August 2009
Art Unit 3686

/Gerald J. O'Connor/
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